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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,257	04/23/2001	Robert A. Scott	6512-11EJF	7160
29668	7590	06/02/2004	EXAMINER	
PFIZER, INC.			HON, SOW FUN	
201 TABOR ROAD			ART UNIT	
MORRIS PLAINS, NJ 07950			PAPER NUMBER	
			1772	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,257

Applicant(s)

SCOTT ET AL.

Examiner

Sow-Fun Hon

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Affidavit

1. The affidavit under 37 CFR 1.132 filed 08/13/03 is insufficient to overcome the rejections of claims based upon US 5,885,617 as set forth in the last Office action because: the specific composition in Example 1 of Applicant to generate the comparison data is not recited in the present claims. Thus the data is not commensurate in scope with the claims.

Withdrawn Claim Objections

2. The claim objections in the Office action dated 02/27/04 have been withdrawn due to the amendment filed 02/17/04.

Rejections Repeated

3. The 35 U.S.C 102(b) and 103(a) rejections of claims 57-81 are repeated for the same reasons previously of record in the Office action dated 02/27/03.

Response to Arguments

4. Applicant's arguments filed 08/13/03 have been fully considered but they are not persuasive.

5. Applicant argues that Jordan does not disclose a capsule and that the reference discloses a coating for a tablet. Applicant is respectfully apprised that Jordan teaches that the liquid solution is sprayed onto the pharmaceutical tablets, inherently forming a capsule molded into the shape of the tablet underneath it (column 3, lines 50-60).

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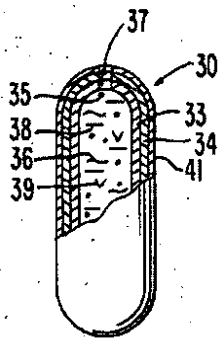
6. Applicant argues that Jordan does not teach or suggest the use of a setting system.

Applicant is respectfully apprised that Jordan teaches the addition of alginates and natural gums (column 2, lines 60-65) which are setting agents according to Applicant's specification (original claim 7).

7. Applicant argues that Jordan is merely looking to use polyvinyl alcohol as a low water permeability agent. Applicant is respectfully apprised that a capsule is an encapsulant, which is the same as a formed coating on the tablet.

8. Applicant submits a declaration comparing composition made according to the present application and composition made according to Jordan, wherein the composition made according to Jordan is not capable of sitting on capsule making mold pins. Applicant is respectfully apprised that the composition in Example 1 of Applicant is not recited in the present claims. As stated above, the data is not commensurate with the scope of the present claims.

9. Applicant argues that Deters discloses the type of capsule which is formed from two separate components, maintained as separate components in the capsule system, whereas the present application is directed to a unitary capsule formed from a PVA solution containing PVA and the setting system (a hydrocolloid).



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Applicant is respectfully apprised that Deters teaches a capsule of polyvinyl alcohol (column 9, lines 10-30) lamina 33, coated with a hydroxypropyl methylcellulose phthalate (column 8, lines 20, 40-60), lamina 34 (column 8, lines 10-25). See figure above. This is accordance with the structural recitation in Applicant's claims of a capsule having at least one coating thereon (claim 58) made from a substance selected from the group which includes hydroxypropyl methylcellulose phthalate (claim 59). Deters et al. fails to teach the setting agent of hydrocolloids which is compensated by Yamamoto et al. Yamamoto et al. discloses prior art which teaches polyvinyl alcohol as a film forming polymer for hard capsules (column 1, lines 55-60) where the capsule molding steps of the prior art failed (column 1, lines 60-70) due to the inability of the composition to set (gelate) at room temperature (column 2, lines 50-55). It can then be inferred that the amounts of setting (gelatinizing) agent, cations and water taught by Yamamoto et al. would form a superior capsule when added to the polyvinyl alcohol of the prior art, and hence to the composition of Deters et al.

10. Applicant argues that the combination of Jordan in view of Yamamoto et al. does not stand because Jordan is not directed to a capsule forming system and Yamamoto teaches how to make capsules using cellulose ethers as the principal component, such that the combination does not lead to a capsule in which PVA is the principle component for its low water vapor permeability properties without detracting from those properties by using a significant amount of a gelling agent such as cellulose ether.

Applicant is respectfully apprised that Jordan is the primary reference which teaches the polyvinyl alcohol as the film forming polymer for encapsulating (coating) tablets, comprising alginates (column 3, lines 1-10) which is a setting agent according to Applicant's specification

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(original claim 7). Jordan fails to teach kappa-carrageenan as one of the setting agents.

Yamamoto et al. is the compensating secondary reference which teaches kappa-carrageenan as a setting agent, and discloses prior art which teaches polyvinyl alcohol as a film forming polymer for hard capsules (column 1, lines 55-60) where the capsule molding steps of the prior art failed (column 1, lines 60-70) due to the inability of the composition to set (gelate) at room temperature (column 2, lines 50-55). It can then be inferred that the amounts of setting (gelatinizing) agent, cations and water taught by Yamamoto et al. would form a superior capsule when applied to the polyvinyl alcohol capsule of the prior art, and hence to the composition of Jordan.

11. Applicant argues that the same arguments against the use of Jordan as a primary reference apply against the combination of Jordan in view of Frensch. These arguments have been addressed above.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sow-Fun Hon

05/27/04


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

5/28/04